MAY 12 2006

II. Safety and Efficacy Summary

K060116

A. *Contact Information*

Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Endovascular Corporation
610 Palomar Avenue
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B. *Device Name*

Micrus Microcatheters, Courier," 165, 170, 190, & 210
Device: Catheter, Intravascular, Diagnostic
Regulation Number: 870.1200
Product Code: DQO
Device Class: 2

C. *Predicate Device(s)*

Number	Description	Clearance Date
K032624	Micrus Microcatheter, Concourse-14	Sept 10, 2003

D. *Device Description*

The Micrus Microcatheters consist of 4 major components:

- A flexible shaft with a lubricious liner extruded from Teflon. The shaft is reinforced with stainless steel (coiled distally and braided proximally). The outer shaft jacket is made from Pebax and nylon Grilamid L25).
- An atraumatic distal flexible tip containing two radiopaque marker bands. The marker bands are useful in tracking catheter tip position and during placement of detachable embolic coils.
- A standard luer hub insert, which is molded onto the flexible shaft.
- A hydrophilic coating (Hydromer), which covers the distal 100 centimeters of the Microcatheters.

E. *Intended Use*

The Micrus Courier Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents such as occlusion coils, into peripheral, coronary, and neuro vasculature.

F. Intended Use Predicate Device (per products' Instructions for Use)

The Micrus Microcatheter, Concourse-14 is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents such as occlusion coils, into peripheral, coronary, and neuro vasculature.

G. Technological (Physical and Mechanical) Characteristics as Compared to Predicate

Characteristic	*Predicate: Micrus Concourse-14*	*Micrus Courier 165, 170, 190, & 210*	*Equivalence*
Shaft Materials	Pebax with PTFE liner	Pebax and nylon with PTFE liner	equivalent
Shaft Design	Flexible single lumen shaft. The catheter shaft is made from Pebax with a PTFE liner. The distal flexible tip is atraumatic with 2 radiopaque markers.	Flexible single lumen shaft. The catheter shaft is made from Pebax & nylon with a PTFE liner. The distal flexible tip is atraumatic with 2 radiopaque markers.	Substantially equivalent
Distal Shaft Length *(dry & hydrated states)*	20 to 25 cm	30 to 35 cm	Substantially equivalent
Proximal ID/OD *(dry & hydrated states)*	ID: 0.0165" – 175" OD: 0.031" (2.4 French)	Inner diameters are within specifications: Courier 165 ID is .0165" minimum Courier 170 ID is 0.0170" minimum Courier 190 ID is 0.0190" minimum Courier 210 ID is 0.0210" minimum Outer diameters are within specifications: Courier 165 OD is 0.033" max. (2.3 Fr.) Courier 170 OD is 0.034" max. (2.4 Fr.) Courier 190 OD is 0.042" max. (3.0 Fr.) Courier 210 OD is 0.042" max. (3.0 Fr.)	Substantially equivalent
Distal ID/OD *(Dimensions unchanged in dry & hydrated states)*	ID: 0.0165" OD: 0.025" (1.9 French)	Inner diameters are within specifications: Courier 165 ID is .0165" minimum Courier 170 ID is 0.0170" minimum Courier 190 ID is 0.0190" minimum Courier 210 ID is 0.0210" minimum Outer diameters are within specifications: Courier 165 OD is 0.023" max. (1.7 Fr.) Courier 170 OD is 0.024" max.(1.8 Fr.) Courier 190 OD is 0.032" max. (2.5 Fr.) Courier 210 OD is 0.032" max. (2.5 Fr.)	Substantially equivalent

Shaft Marker	No shaft marker	Shaft marker located at 90 cm from the distal tip.	New feature.
Tip Markers	Two radiopaque marker bands, spaced 3 cm apart.	Two radiopaque marker bands, spaced 3 cm apart.	Substantially equivalent
Coating	Hydrophilic coating.	Hydrophilic coating.	Substantially equivalent
Effective Length *(dry & hydrated states)*	150 cm (59")	150 cm (59")	Substantially equivalent
MicroCoil Compatibility	Coils: Compatible with 10-System embolic coils. Wires: Compatible with 0.010" and 0.014" guide wires.	Coils: Courier 165 & 170 are compatible with 10-System embolic coils; Courier 190 & 210 are compatible with 18-System coils. Wires: Courier 165 & 170 are compatible with 0.010" and 0.014" guide wires; Courier 190 & 210 are compatible with 0.014" and 0.018" guide wires.	Substantially equivalent

H. Discussion of Non-Clinical Tests and Conclusions

The non-clinical tests performed on the Micrus Courier Microcatheters were based upon the intended use of the device, the performance of the predicate microcatheter, and compliance to ISO 10555, "Sterile, single-use intravascular catheters - Part 1: General Requirements."

The following table outlines the important device characteristics and the non-clinical test data generated:

Test or Comparison	*Concourse-14*	*Courier 165, 170, 190, & 210*	*Substantial Equivalence*
Tensile strength and tip attachment strength	The shaft to hub junction has a minimum tensile strength of 1.12 lb (5 Newtons). All transition junctions of the shaft have a minimum tensile strength of 0.67 lb (3 Newtons).	The shaft to hub junction has a minimum tensile strength of 1.12 lb (5 Newtons). All transition junctions of the shaft have a minimum tensile strength of 0.67 lb (3 Newtons).	Substantially Equivalent
Flexibility/Stiffness	Demonstrates adequate flexibility to bend easily when under pressure, such as that exerted by vessel tortuosity.	As compared to the predicate, demonstrates adequate flexibility to bend easily when under pressure, such as that exerted by vessel tortuosity.	Substantially Equivalent
Burst Pressure	Demonstrates a burst strength greater than 300 PSI.	Demonstrates a burst strength greater than 300 PSI.	Substantially Equivalent
Biocompatibility	Materials in the microcatheter successfully pass all biocompatibility testing per ISO 10993-1.	Materials in the microcatheter successfully pass all biocompatibility testing per ISO 10993-1.	Substantially Equivalent
Air leakage at hub	No air leakage during testing with negative pressure applied to the catheter hub per ISO 10555-1.	No air leakage during testing with negative pressure applied to the catheter hub per ISO 10555-1.	Substantially Equivalent
Liquid leakage	Demonstrates there is no liquid leakage during testing at 46.4 PSI (maintained for 30 seconds) per ISO 10555-1.	Demonstrates there is no liquid leakage during testing at 46.4 PSI (maintained for 30 seconds) per ISO 10555-1.	Substantially Equivalent

Fatigue tolerance and catheter material integrity	Catheter advanced and retracted 20 times in a tortuous arterial model with a 150-micron filter in a distal location. No catheter particulate or debris resulted from the rigorous stress placed upon the catheter during advancement and retraction.	Catheter advanced and retracted 20 times in a tortuous arterial model with a 150-micron filter in a distal location. No catheter particulate or debris resulted from the rigorous stress placed upon the catheter during advancement and retraction.	Substantially Equivalent
Chemical Integrity/Corrosion Resistance	Demonstrates corrosion resistance per ISO 10555-1 in saline solution and boiling distilled water.	No change to the design of the Courier microcatheters affected corrosion resistance.	Substantially Equivalent
Material Used	Pebax shaft. PTFE liner. Hydrophilic coating. All materials are biocompatible.	Pebax shaft. PTFE liner. Hydrophilic coating. All materials are biocompatible.	Substantially Equivalent
Labeling	Label content complies with regulatory requirements of all markets where the product is sold. Product labels contain at least 2 removable stickers, which specify the catalog number, lot number and product name.	Label content complies with regulatory requirements of all markets where the product is sold. Product labels contain at least 2 removable stickers, which specify the catalog number, lot number and product name.	Substantially Equivalent
Proximal shaft kink radius	Demonstrates a minimum kink resistant radius of 0.325" in the proximal shaft.	Demonstrates a minimum kink resistant radius of 0.325" in the proximal shaft.	Substantially Equivalent
Distal shaft kink radius	Demonstrates a minimum kink resistant radius of 0.07" in the distal shaft.	Demonstrates a minimum kink resistant radius of 0.07" in the distal shaft.	Substantially Equivalent
Tracking force	Demonstrates the microcatheter is able to track through a tortuous path.	Demonstrates the microcatheter is able to track through a tortuous path with less or equal force (friction) than the predicate	Substantially Equivalent

Tip shape retention	Demonstrates the Microcatheter maintains its tip shape when subjected to 3 hours of soaking in a 37°C. bath.	Demonstrates the Microcatheter maintains its tip shape when subjected to 3 hours of soaking in a 37°C. bath.	Substantially Equivalent
Packaging Integrity	Tyvek Pouch. Sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged. Packaging qualified to prevent microbial recontamination for a minimum of 3-yrs.	Tyvek Pouch. Sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged. The Courier microcatheters use the same packaging as is used for the Concourse microcatheter. The package integrity has been qualified to prevent microbial recontamination for a minimum of 3-yrs.	Equivalent
Shipping/transit testing	Demonstrates the microcatheter successfully withstands the domestic and international distribution environment, per ISO 10555-1.	Demonstrates the microcatheter successfully withstands the domestic and international distribution environment, per ISO 10555-1.	Substantially Equivalent
Sterility	Sterilized using EtO with a sterility assurance level of 10^{-6}	Sterilized using EtO with a sterility assurance level of 10^{-6}	Substantially Equivalent

The above non-clinical testing has demonstrated the substantially equivalent performance of the Micrus Microcatheters, "Courier," with the predicate "Concourse" Microcatheter.
The catheters are single lumen catheters with the same labeling, indications for use, materials, and packaging (as indicated in the above comparison table).

I. 510(k) Summary of Safety and Efficacy

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Micrus Corporation, it is concluded that the "Courier" Microcatheters are substantially equivalent to the "Concourse-14" in safety and effectiveness.

Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Endovascular Corporation
January 9, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2006

Micrus Endovascular Corporation
c/o Ms. Margaret Webber
Director, Regulatory and Clinical Affairs
821 Fox Lane
San Jose, CA 95131

Re: K060116
Micrus Courier Microcatheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Catheter Intravascular, Diagnostic
Regulatory Class: II
Product Code: DQO
Dated: March 31, 2006
Received: April 4, 2006

Dear Ms. Webber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060116

Device Name: Micrus Courier Microcatheters"
Model #s MST165000-00, MST170000-00, MST190000-00, & MST210000-00

Indications For Use:

The Micrus Courier microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents such as occlusion coils, into peripheral, coronary, and neuro vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060116